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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,852	05/04/2001	Jennifer L. Hillman	PF-0515-1 CON	8542

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,852

Applicant(s)

Hillman et al

Examiner

Unger

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 4, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1. Claims 1-49 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claims 1, 2, 17, 18, 46 are drawn to a polypeptide, SEQ ID NO:1 classified in Class 530, subclass 350+.

Group 2. Claims 1, 2, 17, 47 are drawn to a polypeptide, SEQ ID NO:3, classified in Class 530, subclass 350+.

Group 3. Claims 3-7, 9-10, 12-13 and 48 are drawn to polynucleotide, SEQ ID NO:2, classified in Class 536, subclass 23.1.

Group 4. Claims 3-7, 9-10, 12-13 and 49 are drawn to polynucleotide, SEQ ID NO:4, classified in Class 536, subclass 23.1.

Group 5. Claim 8 is drawn to a transgenic organism comprising SEQ ID NO:2, classified in Class 800 subclass 2.

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Group 6. Claim 8 is drawn to a transgenic organism comprising SEQ ID NO:4, classified in Class 800 subclass 2.

Group 7. Claims 11, 31-34, 37-38, 40-41 are drawn to an antibody that binds to SEQ ID NO:1, classified in Class 530, subclasses 387.1, 389.1.

Group 8. Claims 11, 31-34, 37-38, 40-41 are drawn to an antibody that binds to SEQ ID NO:3, classified in Class 530, subclasses 387.1, 389.1.

Group 9. Claims 14 and 15 are drawn to a method of detecting a polynucleotide, SEQ ID NO:2, classified in class 435, subclass 6.

Group 10. Claims 14 and 15 are drawn to a method of detecting a polynucleotide, SEQ ID NO:4, classified in class 435, subclass 6.

Group 11. Claims 16 is drawn to a different method of detecting a polynucleotide, SEQ ID NO:2 classified in Class 435, subclass 6.

Group 12. Claims 16 is drawn to a different method of detecting a polynucleotide, SEQ ID NO:4 classified in Class 435, subclass 6.

Group 13. Claim 19 is drawn to a method of treating a disease or condition comprising administering SEQ ID NO:1, classified in Class 514, subclass 2.

Group 14. Claim 19 is drawn to a method of treating a disease or condition comprising administering SEQ ID NO:3, classified in Class 514, subclass 2.

Group 15. Claim 20 is drawn to a method of screening for an agonist of SEQ ID NO:1, classified in Class 435, subclass 4.

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Group 16. Claim 20 is drawn to a method of screening for an agonist of SEQ ID NO:3, classified in Class 435, subclass 4.

Group 17. Claim 21 is drawn to an agonist of SEQ ID NO:1, classified in Class 530, subclass 300+.

Group 18. Claim 21 is drawn to an agonist of SEQ ID NO:3, classified in Class 530, subclass 300+.

Group 19. Claim 22 is drawn to an method of treating a disease or condition with an agonist of SEQ ID NO:1, classified in Class 514, subclass 2.

Group 20. Claim 22 is drawn to an method of treating a disease or condition with an agonist of SEQ ID NO:3, classified in Class 514, subclass 2.

Group 21. Claim 23 is drawn to a method of screening for an antagonist of SEQ ID NO:1, classified in Class 435, subclass 4.

Group 22. Claim 23 is drawn to a method of screening for an antagonist of SEQ ID NO:3, classified in Class 435, subclass 4.

Group 23. Claim 24 is drawn to an antagonist of SEQ ID NO:1, classified in Class 530, subclass 300+.

Group 24. Claim 24 is drawn to an antagonist of SEQ ID NO:3, classified in Class 530, subclass 300+.

Group 25. Claim 25 is drawn to an method of treating a disease or condition with an agonist of SEQ ID NO:1, classified in Class 514, subclass 2.

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Group 26. Claim 25 is drawn to an method of treating a disease or condition with an agonist of SEQ ID NO:3, classified in Class 514, subclass 2.

Group 27. Claim 26 is drawn to a method of screening for a binder of SEQ ID NO:1, classified in Class 435, subclass 4.

Group 28. Claim 26 is drawn to a method of screening for a binder of SEQ ID NO:3, classified in Class 435, subclass 4.

Group 29. Claim 27 is drawn to a method of screening for a modulator of SEQ ID NO:1, classified in Class 435, subclass 4.

Group 30. Claim 27 is drawn to a method of screening for a modulator of SEQ ID NO:3, classified in Class 435, subclass 4.

Group 31. Claim 28 is drawn to a method of screening for a compound for effectiveness at altering expression of SEQ ID NO:2, classified in Class 435, subclass 6.

Group 32. Claim 28 is drawn to a method of screening for a compound for effectiveness at altering expression of SEQ ID NO:4, classified in Class 435, subclass 6.

Group 33. Claim 29 is drawn to a method of screening for a toxicity of a compound that hybridizes to SEQ ID NO:2, classified in Class 435, subclass 6.

Group 34. Claim 29 is drawn to a method of screening for a toxicity of a compound that hybridizes to SEQ ID NO:4, classified in Class 435, subclass 6.

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Group 35. Claim 30 is drawn to a method of in vitro diagnosis comprising identifying SEQ ID NO:1, classified in Class 435, subclass 7.1.

Group 36. Claim 30 is drawn to a method of in vitro diagnosis comprising identifying SEQ ID NO:3, classified in Class 435, subclass 7.1.

Group 37. Claims 33 and 35 are drawn to a method of in vivo diagnosis comprising identifying SEQ ID NO:1, classified in Class 435, subclass 7.1.

Group 38. Claims 33 and 35 are drawn to a method of in vivo diagnosis comprising identifying SEQ ID NO:3, classified in Class 435, subclass 7.1.

Group 39. Claim 36 is drawn to a method of making a polyclonal antibody to SEQ ID NO:1, classified in Class 530, subclass 350+.

Group 40. Claim 36 is drawn to a method of making a polyclonal antibody to SEQ ID NO:3, classified in Class 530, subclass 350+.

Group 41. Claim 39 is drawn to a method of making a monoclonal antibody to SEQ ID NO:1, classified in Class 530, subclass 350+.

Group 42. Claim 39 is drawn to a method of making a monoclonal antibody to SEQ ID NO:3, classified in Class 530, subclass 350+.

Group 43. Claim 42 is drawn to a different method of making an antibody to SEQ ID NO:1, classified in Class 530, subclass 350+.

Group 44. Claim 42 is drawn to a different method of making an antibody to SEQ ID NO:3, classified in Class 530, subclass 350+.

Group 45. Claim 43 is drawn to a different method of making an antibody to SEQ ID NO:1, classified in Class 530, subclass 350+.

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Group 46. Claim 43 is drawn to a different method of making an antibody to SEQ ID NO:3, classified in Class 530, subclass 350+.

Group 47. Claim 44 is drawn to a method of detecting a polypeptide, SEQ ID NO:1, classified in Class 435, subclass 7.1.

Group 48. Claim 44 is drawn to a method of detecting a polypeptide, SEQ ID NO:3, classified in Class 435, subclass 7.1.

Group 49. Claim 45 is drawn to a method of purifying a polypeptide, SEQ ID NO:1, classified in Class 435, subclass 7.1.

Group 50. Claim 45 is drawn to a method of purifying a polypeptide, SEQ ID NO:3, classified in Class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-8, 17-18 and 23-24 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 9-16, 19-22, 25-50 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1/2 and 27-30, 35-46 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see

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MPEP § 806.05(h)]. In the instant case the polypeptide product claimed can be used in a materially different process such as a molecular weight marker in western blot analysis.

The inventions of Groups 3/4 and 9-12 and 31-34 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the polynucleotide product claimed can be used in a materially different process such as a molecular weight marker in Southern blot analysis.

The inventions of Groups 7/8 and 47-50 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antibody product claimed can be used in a materially different process such as the production of anti-idiotypic antibodies.

The inventions of Groups 17/18 and 15-16 and 19-20 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see

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MPEP § 806.05(h)]. In the instant case the agonist product claimed can be used in a materially different process such as a molecular weight marker in western blot analysis.

The inventions of Groups 23/24 and 21-22 and 25-26 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antagonist product claimed can be used in a materially different process such as a molecular weight marker in western blot analysis.

The inventions of Groups 1/2 and 9-16, 19-22, 25-26, 31-34, 47-50 are not at all related because the polypeptide of Group 1/2 is not used in any of the methods of Groups 9-16, 19-22, 25-26, 31-34, 47-50.

The inventions of Groups 3/4 and 13-16, 19-22, 15-30, 35-50 are not at all related because the polypeptide of Group 3/4 is not used in any of the methods of Groups 13-16, 19-22, 15-30, 35-50.

The inventions of Groups 5/6 and 9-16, 19-22, 25-50 are not at all related because the transgenic organism of Group 5/6 is not used in any of the methods of Groups 9-16, 19-22, 25-50.

The inventions of Groups 7/8 and 9-16, 19-22, 25-46 are not at all related because the antibody of Group 7/8 is not used in any of the methods of Groups 9-16, 19-22, 25-46.

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The inventions of Groups 17/18 and 9-14, 21-22, 25-50 are not at all related because the agonist of Group 17/18 is not used in any of the methods of Groups 9-14, 21-22, 25-50.

The inventions of Groups 23/24 and 9-16, 19-20, 27-50 are not at all related because the antagonist of Group 23/24 is not used in any of the methods of Groups 9-16, 19-20, 27-50.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R.

§ 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

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order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

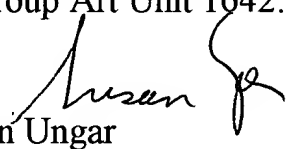
7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar
Primary Patent Examiner
September 26, 2002